

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

---

In re Patent Application of:

Satishchandra P. Patel

Application No.: 10/632,970

Confirmation No.: 4466

Filed: August 4, 2003

Art Unit: 1618

For: PHARMACEUTICAL COMPOSITIONS

Examiner: S. T. Tran

**APPELLANT'S REPLY**

MS Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This short Reply Brief is being submitted to respond to certain assertions made in the Examiner's Answer mailed March 14, 2008.

The Examiner's Answer relies on sophistry. The Appeal Brief pointed out that while the Mulye reference and the appealed application concern percentages, one does so in terms of weight percent while the other is in terms of mol percent. Converting weight percent into mol percent (or vice versa) is a routine exercise but the Examiner's Answer refuses to do so.

The Examiner's Answer does refer to mol and weight percent when repeating applicant's arguments but when responding to them, it ignores the difference and simply refers to "percent." See, e.g., pg. 5, lns. 3-4. That is grossly improper and misleading. It is like reporting temperature solely in terms of "degrees" -- at 35°F, one puts on an overcoat whereas at 35°C, a bathing suit is more appropriate. Like the conversion

between Fahrenheit and Centigrade, the conversion between mol percent and weight percent is a simple mathematical exercise.

In response to the applicant's statement that Mulye requires at least about 60 wt % monoester while the invention uses less than 50 wt %, the Examiner's Answer on page 4 replies "that the feature upon which Applicant relies (i.e., less than 50% monoester) is not recited in the rejected claims", an assertion based on the fact that "the present claims require monoester of between 50% and 60%." (pg. 5, ln. 3) As shown in the Appeal Brief, a 60 mole % content of the propylene glycol monoester of a C<sub>8</sub> fatty acid in a mixture with propylene glycol C<sub>8</sub> fatty acid diester corresponds to 48 wt %. The corresponding conversions to the weight percents for the C<sub>9</sub> and C<sub>10</sub> fatty acid monoesters are even lower. Thus, the claim recitation that the top of the range is 60 mol % is the very same thing as saying that the top of the range is 48 wt % monoester. The assertion "that ... less than 50% monoester... is not recited in the rejected claims" may be technically true but it is substantively false because those claims do not refer to "50 %" but rather recite 48 wt % (60 mol %).

Mulye points out again and again that the monoester must be at least 60% by weight and this amount is "essential." A value of 60% by weight corresponds to a value in excess of 70 mol %. That is far above 60 mol %.

While the word "about" indicates that there is some leeway in Mulye's 60 wt %, it is still much greater than the amount in the instant claims. On page 5 of the Examiner's Action, the minimum "about 60 wt %" is construed as including anything starting at 55 wt %. In the Advisory Action, it was asserted to be as low as 58 %. Those assertions are consistent with Mulye's comparative examples, where 50 wt % monoester showed precipitation and crystal growth while 60 wt % monoester formulation did not (pg. 35, Ins. 14-18); Clearly, "about 60 wt %" is larger than 50 wt %.

But, 55 wt % (or 58 %) is much greater than 48 wt % (recited in the appealed claims as 60 mol %).

The Examiner's Answer argues that it is not inventive to discover the optimum or workable ranges by routine experimentation, citing the 1955 court decision. This argument ignores the fact 17 years later the same court held that "while it may ordinarily be the case that determination of optimum values for the parameters of a prior art process would be at least *prima facie* obvious, that conclusion depends on what the prior art discloses with respect to those parameters. Where, as here, the prior art disclosure suggests the outer limits of the range are suitable values, and that the optimum resides within that range, ... the determination of optimum values outside that range may not be obvious." *In re Sebek*, 175 U.S.P.Q. 93, 95 (C.C.P.A 1972). In this Appeal, the prior art teaches the critical minimum amount of the monoester is about 60 wt % and the optimum is about 90 wt %. Determination that the amount should be less than 50 wt % when the ester group has a particular carbon atom range, as recited in the appealed claims, is clearly unexpected and not predictable.

For the reasons set forth in the Appeal Brief and in this Reply Brief, the rejection is untenable and should be reversed.

Dated: March 28, 2008

Respectfully submitted,

By /Edward A. Meilman/  
Edward A. Meilman  
Registration No.: 24,735  
DICKSTEIN SHAPIRO LLP  
1177 Avenue of the Americas  
New York, New York 10036-2714  
(212) 277-6500  
Attorney for Applicant